

# **Medicare Payment for Drugs and Biologics**

**Rare Plasma Protein Disorders  
FDA Workshop June 13-14, 2005  
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# Overview

- Statutory payment systems, treatment settings, and types of blood products
- Medicare Modernization Act (MMA)
- New Average Sales Price (ASP) and Competitive Acquisition programs
- New IVIG Home Infusion benefit

# Medicare Modernization Act (MMA)

- Public Law 109-173, December 8, 2003
- Social Security Act (SSA) – “The Act”  
Title XVIII – authority for Medicare  
“Health Insurance for Aged and Disabled”
- Changes drug payment methodology
- Adds benefit for IVIG home infusion

# Treatment Settings

- Inpatient Hospital – DRGs
- Hospital Outpatient Prospective Payment System (HOPPS) - APCs
- Physician Office – “incident to ...”
- Home Infusion – per MMA Section 642  
(only for Primary Immune Deficiencies)

## Payment for Blood Products Based on Product Type and Setting

<b>PRODUCT SETTING</b>	<b>BLOOD</b>	<b>PLASMA &amp; DRUGS</b>	<b>CLOTTING FACTORS</b>
<b>INPT</b>	DRG	DRG	95% AWP
<b>HOPPS</b>	APC	MMA	MMA
<b>Physician Office</b>	Unchanged	ASP + 6%	ASP + 6% + 14c/unit

# HOPPS Drug Payments - 2005

- MMA 621 amends SSA 1833(t)
- Sole Source: 83% < \$ < 95% AWP
- Multi-Source Innovator: \$ < 68% AWP
- Multi-Source Non-innovator: \$ < 46% AWP
- 2006 and beyond:
  1. ave. acquisition cost per GAO survey
  2. or (w/o survey) ASP method (proxy)

# HOPPS - Drug Categories

## Section 1833(t)(14)(F)

- **Sole Source**
  - 1. biologic - Sec 1861(t)(1), or**
  - 2. single source drug - Sec 1927(k)(7)(A)(iv)**  
**originally marketed under FDA NDA**
- **MS Innovator – Sec 1927(k)(7)(A)(ii)**  
**originally marketed under FDA NDA**
- **MS Non-innovator – Sec 1927(k)(7)(A)(iii)**  
**MS but not a MS Innovator drug**

## HOPPS – Drug Exceptions

### **Sect 1833(t)(14)(B)(ii)**

- Payment first made after Jan 1, 2003
- No temporary HCPCS code assigned
- Orphan Drugs (in 2004 and 2005)

**2005: higher of 88% AWP or ASP + 6%**

**2006: pending HOPPS Proposed Rule**



# Physician Drug Payments (incident to physician services)

- **MMA 303(b) amends SSA 1842(o)(1)**
- **MMA 303(c) adds SSA 1847A (new)**
- **SSA 1847A: “Average Sales Price” (ASP)**
- **Sole Source Drug: basis amount is lesser of ASP or “Wholesale Acquisition Cost” (WAC)**
- **Physician payment is basis amount + 6 %**

## “Single Source Drug”

- Biological, or
- Drug
  1. not a Multiple Source drug
  2. distributed under FDA NDA

## Exceptions to “ASP” method **Sect 1842(o)(1)**

- Infusion drugs thru DME – 95% AWP or DME comp acq after Jan 1, 2007
- Separately billed dialysis drugs/biologics
- Blood and blood products – no change
- Vaccines per Sect 1861(s)(10)(A) or (B)
- No exception for Orphan Drugs

# ASP Method

- SSA 1847A(c)(1) ASP for drug or biologic
- Manufacturer's sales (\$) to all purchasers divided by total number of units sold
- Certain sales exempted from calculations
- Sales price net of discounts and rebates

# WAC Method

- SSA 1847A(c)(6)(B) WAC for drug/biologic
- Manufacturer's list price for the drug to wholesalers or direct purchasers
- Excludes prompt pay or other discounts, rebates or reductions in price
- Reported in wholesale price guides or other publications of drug pricing data

# Competitive Acquisition

- MMA 303(c) adds SSA 1847B (new)
- Begins phased roll-out January 1, 2006
- Physician selects payment method each yr
- Exclusions per Secretary discretion for
  1. no significant savings to Medicare, or
  2. adverse impact on access to products

# **IVIG Home Infusions for Primary Immune Diseases**

- MMA Sec 642 amends SSA 1861(s) and adds SSA 1861(zz) (new) effective 2004
- Payment method: ASP + 6%
- Part B deductibles and co-pays apply
- Excludes administration items & services
- Pharmacies, hosp, physicians bill DMERC
- HH Agencies bill Regional HH Intermed.

## **New IVIG HCPCS Codes effective April 1, 2005**

- Q9941 - IVIG lyophilized, 1 gram
- Q9942 - IVIG lyophilized, 10 mg
- Q9943 - IVIG non-lyophilized, 1 gram
- Q9944 - IVIG non-lyophilized, 10 mg
- J1563 - Inactive for Medicare payment
- J1564 - Inactive for Medicare payment



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